

Do not use beyond the expiration date on the container. HUMIRA must be refrigerated at 2 to 8° C (36 to 46° F). DO NOT FREEZE. Protect the prefilled syringe from exposure to light. Store in original carton until time of administration.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

17.1 Patient Counseling

Patients should be advised of the potential benefits and risks of HUMIRA. Physicians should instruct their patients to read the Medication Guide before starting HUMIRA therapy and to reread each time the prescription is renewed.

- **Immunosuppression**

Inform patients that HUMIRA may lower the ability of their immune system to fight infections. Instruct the patient of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections.

Patients should be counseled about the risk of lymphoma and other malignancies while receiving HUMIRA.

- **Allergic Reactions**

Patients should be advised to seek immediate medical attention if they experience any symptoms of severe allergic reactions. Advise latex-sensitive patients that the needle cap of the prefilled syringe contains latex.

- **Other Medical Conditions**

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

17.2 Instruction on Injection Technique

The first injection should be performed under the supervision of a qualified health care professional. If a patient or caregiver is to administer HUMIRA, he/she should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of HUMIRA [*see Medication Guide (17)*].

A puncture-resistant container for disposal of needles and syringes should be used. Patients or caregivers should be instructed in the technique as well as proper syringe and needle disposal, and be cautioned against reuse of these items.

MEDICATION GUIDE

MEDICATION GUIDE

HUMIRA® (HU-MARE-AH)

(adalimumab)

Read the Medication Guide that comes with HUMIRA before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment with HUMIRA.

What is the most important information I should know about HUMIRA?

HUMIRA is a medicine that affects your immune system. HUMIRA can lower the ability of the immune system to fight infections. **Serious infections have happened in patients taking HUMIRA. These infections include tuberculosis (TB) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.**

- Your doctor should test you for TB before starting HUMIRA.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with HUMIRA.

Before starting HUMIRA, tell your doctor if you:

- think you have an infection. You should not start taking HUMIRA if you have any kind of infection.
- are being treated for an infection
- have signs of an infection, such as a fever, cough, or flu-like symptoms
- have any open cuts or sores on your body
- get a lot of infections or have infections that keep coming back
- have diabetes
- have TB, or have been in close contact with someone with TB
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your doctor.
- have or have had hepatitis B
- use the medicine Kineret (anakinra). You may have a higher chance for serious infections and a low white blood cell count when taking HUMIRA with Kineret.
- are scheduled to have major surgery

After starting HUMIRA, call your doctor right away if you have an infection, or any sign of an infection, including:

- a fever
- feel very tired
- a cough
- flu-like symptoms
- warm, red, or painful skin
- open cuts or sores on your body

HUMIRA can make you more likely to get infections or make any infection that you may have worse.

Certain types of Cancer.

- There have been cases of unusual cancers in children and teenage patients using TNF-blocking agents.
- For children and adults taking TNF-blocker medicines, including HUMIRA, the chances of getting lymphoma or other cancers may increase.
- Some patients receiving HUMIRA have developed types of cancer called non-melanoma skin cancer (basal cell cancer and squamous cell cancer of the skin), which are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that doesn't heal.
- Patients with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.

See the section “What are the possible side effects of HUMIRA?” below for more information.

What is HUMIRA?

HUMIRA is a medicine called a Tumor Necrosis Factor (TNF) blocker. HUMIRA is used in adults or children (as indicated) to:

- Reduce the signs and symptoms of:
 - **moderate to severe rheumatoid arthritis (RA)** in adults. HUMIRA can be used alone or with methotrexate or with certain other medicines. HUMIRA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **moderate to severe polyarticular juvenile idiopathic arthritis (JIA)** in children 4 years of age and older. HUMIRA can be used alone or with methotrexate or with certain other medicines.
 - **psoriatic arthritis (PsA)**. HUMIRA can be used alone or with certain other medicines. HUMIRA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - **ankylosing spondylitis (AS)**

- **moderate to severe Crohn's disease (CD)** in adults who have not responded well to other treatments.
- **Treat moderate to severe chronic (lasting a long time) plaque psoriasis (Ps)** in adults who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).

People with these diseases have too much of a protein called tumor necrosis factor (TNF) in the affected areas of the body. HUMIRA can block the bad effects of TNF in those affected areas, but it can also lower the ability of the immune system to fight infections. See **“What is the most important information I should know about HUMIRA?”** and **“What are the possible side effects of HUMIRA?”**

What should I tell my doctor before taking HUMIRA?

Before starting HUMIRA, tell your doctor about all of your health conditions, including if you:

- have an infection. See **“What is the most important information I should know about HUMIRA?”**
- have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome.
- have heart failure or other heart conditions. If you have heart failure, it may get worse while you are taking HUMIRA.
- have recently received or are scheduled to receive a vaccine. Patients receiving HUMIRA should not receive live vaccines.
- are allergic to rubber or latex. The needle cover on the prefilled syringe contains dry natural rubber. Tell your doctor if you have any allergies to rubber or latex.
- are allergic to HUMIRA or to any of its ingredients. See the end of this Medication Guide for a list of ingredients in HUMIRA.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. HUMIRA should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use HUMIRA.

Pregnancy Registry: Abbott Laboratories has a registry for pregnant women who take HUMIRA. The purpose of this registry is to check the health of the pregnant mother and her child. Talk to your doctor if you are pregnant and contact the registry at 1-877-311-8972.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Especially, tell your doctor if you take Kineret (anakinra). You may have a higher chance for serious infections and a low white blood cell count when taking HUMIRA with Kineret. Also, tell your doctor if you are taking other medicines that suppress the immune system.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take HUMIRA?

See the section, “**How do I prepare and give an injection of HUMIRA?**” at the end of this Medication Guide for complete instructions for use.

- HUMIRA is given by an injection under the skin. Your doctor will tell you how often to take an injection of HUMIRA. This is based on your condition to be treated. **Do not inject HUMIRA more often than prescribed.**
- Make sure you have been shown how to inject HUMIRA before you do it yourself. You can call your doctor or 1-800-4HUMIRA (448-6472) if you have any questions about giving yourself an injection. Someone you know can also help you with your injection.
- If you take more HUMIRA than you were told to take, call your doctor.
- Do not miss any doses of HUMIRA. If you forget to take HUMIRA, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. This will put you back on schedule. To help you remember when to take HUMIRA, you can mark your calendar ahead of time with the stickers provided in the back of the Medication Guide.

What are the possible side effects of HUMIRA?

HUMIRA can cause serious side effects, including:

See “**What is the most important information I should know about HUMIRA?**”

- **Serious infections.**
Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with HUMIRA and during treatment with HUMIRA. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are taking HUMIRA. Patients who had a negative TB skin test before receiving HUMIRA have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking HUMIRA:
 - cough that does not go away
 - low grade fever
 - weight loss
 - loss of body fat and muscle (wasting)
- **Allergic reactions.** Signs of a serious allergic reaction include a skin rash, a swollen face, or trouble breathing.
- **Hepatitis B virus reactivation in patients who carry the virus in their blood.** In some cases patients have died as a result of hepatitis B virus being reactivated. Your doctor should monitor you carefully during treatment with HUMIRA if you carry the hepatitis B virus in your blood. Tell your doctor if you have any of the following symptoms:

- feel unwell
 - poor appetite
 - tiredness (fatigue)
 - fever, skin rash, or joint pain
- **Nervous system problems.** Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
 - **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
 - **New heart failure or worsening of heart failure you already have.** Symptoms include shortness of breath or swelling of your ankles or feet or sudden weight gain.
 - **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that gets worse in the sun. Symptoms may go away when you stop HUMIRA.
 - **Psoriasis.** Some people using HUMIRA had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with HUMIRA.

Call your doctor or get medical care right away if you develop any of the above symptoms. Your treatment with HUMIRA may be stopped.

Common side effects with HUMIRA include:

- **Injection site reactions** such as redness, rash, swelling, itching, or bruising. These symptoms usually will go away within a few days. If you have pain, redness or swelling around the injection site that doesn't go away within a few days or gets worse, call your doctor right away.
- **Upper respiratory infections** (including sinus infections)
- **Headaches**
- **Rash**
- **Nausea**

These are not all the possible side effects with HUMIRA. Tell your doctor if you have any side effect that bothers you or that does not go away. Ask your doctor or pharmacist for more information.

How do I store HUMIRA?

- Store HUMIRA in a refrigerator at 36 to 46°F (2 to 8°C) in the original container until it is used. Protect from light. **Do not freeze HUMIRA.** Refrigerated HUMIRA remains okay to use until the expiration date printed on the prefilled syringe or Pen. If you need to take HUMIRA with you, such

as when traveling, store it in a cool carrier with an ice pack and protect it from light. If your HUMIRA has been frozen, do not use it, even after it has thawed. Do not use a Pen or prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it. For additional information or questions, you can call 1-800-4HUMIRA (448-6472).

- Do not drop or crush HUMIRA. The prefilled syringe is glass.
- **Keep HUMIRA, injection supplies, and all other medicines out of the reach of children.**

General information about HUMIRA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HUMIRA for a condition for which it was not prescribed. Do not give HUMIRA to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about HUMIRA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about HUMIRA that was written for healthcare professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information go to www.HUMIRA.com or you can enroll in a patient support program by calling 1-800-4HUMIRA (448-6472).

What are the ingredients in HUMIRA?

Active ingredient: adalimumab

Inactive ingredients: sodium phosphate, sodium citrate, citric acid, mannitol, and polysorbate 80.

Patient Instructions for Use

What do I need to do to prepare and give an injection of HUMIRA?

HUMIRA comes as:

1. a single-use pen (HUMIRA PEN) containing a prefilled syringe
2. a single-dose prefilled syringe (HUMIRA)

Follow the directions below for your dose form.

IF YOU ARE USING THE HUMIRA PEN

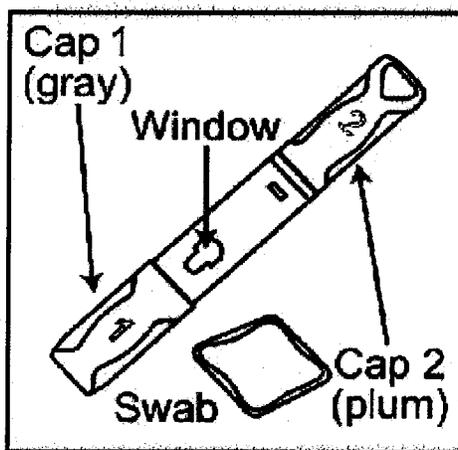
1) Setting up for an injection

- Find a clean flat surface.

- Do not use if the seals on top and bottom of carton are broken or missing. Contact your pharmacist if the seals are broken.
- Take one dose tray containing a HUMIRA Pen from the refrigerator. Do not use a Pen that has been frozen or if it has been left in direct sunlight.

You will need the following items for each dose:

- 1 HUMIRA Pen
- 1 alcohol prep (swab)
- 1 cotton ball or gauze pad (not included in your HUMIRA box)



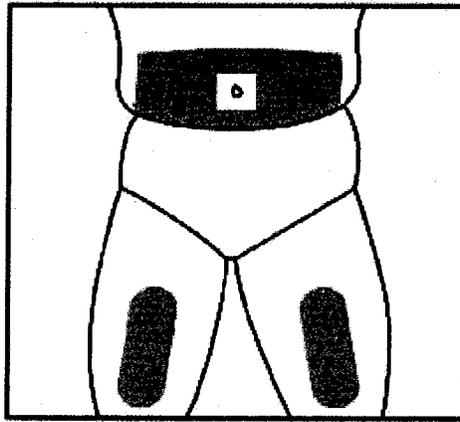
If you do not have all of the items you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA comes in.

- Check and make sure the name HUMIRA appears on the dose tray and Pen label.
- Check the expiration date on the dose tray label and the Pen label to make sure the date has not passed. Do not use a Pen if the date has passed.
- Have a special sharps (puncture proof) container nearby for disposing of the used Pen.

For your protection, it is important that you follow these instructions.

2) Choosing and preparing an injection site

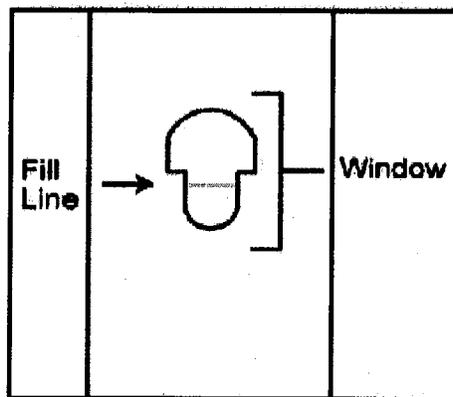
- Wash your hands well



- Choose a site on the front of your thighs or your stomach area (abdomen). If you choose your abdomen, you should avoid the area 2 inches around your belly button (navel).
 - Choose a different site each time you give yourself an injection. Each new injection should be given at least one inch from a site you used before. **Never** inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.
 - If you have psoriasis, you should try not to inject directly into any raised, thick, red or scaly skin patches or lesions.
 - You may find it helpful to keep notes on the location of your injection sites.
- Wipe the site where HUMIRA is to be injected with an alcohol prep (swab), using a circular motion. **Do not** touch this area again until you are ready to inject.

3) How to prepare your HUMIRA dose for injection with a HUMIRA Pen

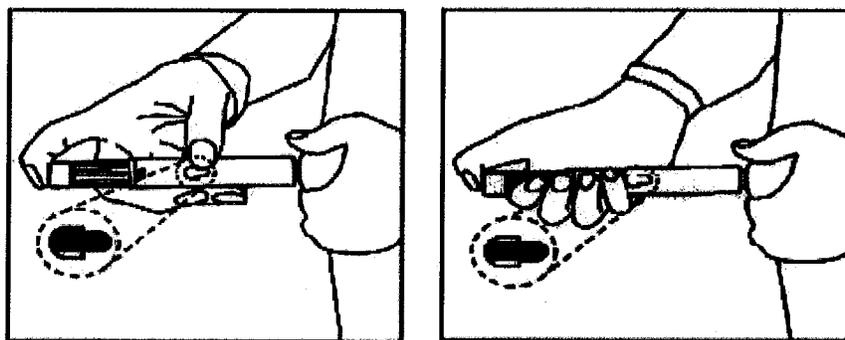
- Hold the Pen with the gray cap pointing up. Check the solution through the windows on the side of the Pen to make sure the liquid is clear and colorless. Do not use a Pen if the liquid is cloudy or discolored or has flakes or particles in it. Do not use if frozen.



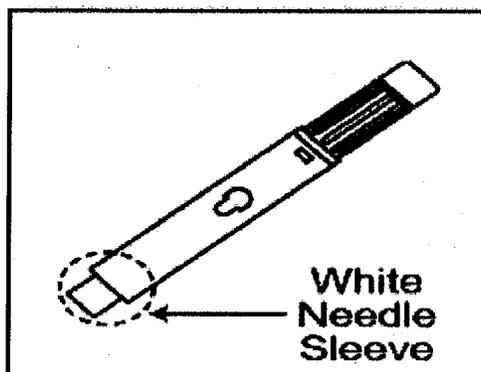
- Turn the Pen over and hold the Pen with the gray cap pointed down. Check to make sure that the amount of liquid in the Pen is the same or close to the fill line seen through the window. The fill line represents a full dose of the product. The top of the liquid may be curved. If the Pen does not have the full amount of liquid, **do not use that pen**. Call your pharmacist.

4) Injecting HUMIRA

- Hold the Pen with one hand. With your other hand, remove the gray cap (1) and discard cap. Pull the cap straight off. Do not twist the cap. Check that the small gray needle cover of the syringe has come off with the cap. After removal, the needle cover is held in the cap. Do not touch the needle. The white needle sleeve, which covers the needle, can now be seen. **Do not put the gray cap (1) back on** or you may damage the needle. Do not drop or crush the product as it contains a glass syringe that may break.
- Remove the plum colored safety cap (2) to expose the plum colored push button at the top. Pull the cap straight off. Do not twist the cap. The Pen is now ready to use. Please note that the Pen is activated after removing the plum colored safety cap 2 and that pressing the button under the plum colored safety cap 2 will release the medicine from the syringe. Do not press the button until you are ready to inject HUMIRA. **Do not put the plum colored cap (2) back on the pen as this could cause medicine to come out of the syringe.**
- Hold the Pen so that the window can be seen.
- With your free hand, gently squeeze an area of the cleaned skin at the injection site. You will inject into this raised area of skin.
- Place the white end of the Pen straight (a 90° angle) and flat against the raised area of skin. Place the Pen so that it will not inject the needle into your fingers that are holding the raised skin.



- With your first (index) finger, press the plum colored button to begin the injection. You may also use your thumb to press the plum colored button to begin the injection. Try not to cover the window. You will hear a ‘click’ when you press the button, which means the start of the injection. Keep pressing the button and continue to hold the Pen against the raised skin until all of the medicine is injected. This can take up to 10 seconds. It is important to keep holding the pen against the raised skin of your injection site for the whole time.
- You will know that the injection has finished when the yellow marker appears fully in the window view and stops moving.



- When the injection is finished, pull the Pen from the skin. The white needle sleeve will move to cover the needle tip.
- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **not** rub the injection site. You may have slight bleeding. This is normal.
- Dispose of the Pen right away into your special sharps container.
- Do not try to touch the needle. The white needle sleeve is there to prevent you from touching the needle. (See “How Do I Dispose of Syringes and Needles?”)

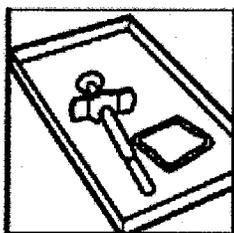
IF YOU ARE USING THE SINGLE-DOSE PREFILLED SYRINGE

1) Setting up for an injection

- Find a clean flat surface.
- Do not use if the seals on top and bottom of carton are broken or missing. Contact your pharmacist if the seals are broken.
- Take one dose tray containing a prefilled syringe of HUMIRA from the refrigerator. Do not use a prefilled syringe that has been frozen or if it has been left in direct sunlight.

You will need the following items for each dose:

- A dose tray containing a prefilled syringe of HUMIRA with a fixed needle
- 1 alcohol prep (swab)
- 1 cotton ball or gauze pad (not included in your HUMIRA box)

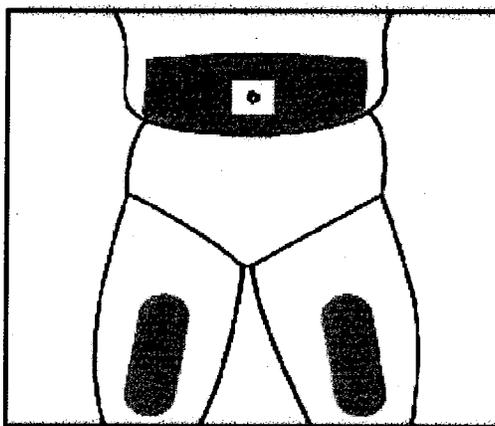


If you do not have all of the items you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA comes in.

- Check and make sure the name HUMIRA appears on the dose tray and prefilled syringe label.
- Check the expiration date on the dose tray label and prefilled syringe to make sure the date has not passed. Do not use a prefilled syringe if the date has passed.
- Make sure the liquid in the prefilled syringe is clear and colorless. Do not use a prefilled syringe if the liquid is cloudy or discolored or has flakes or particles in it.
- Have a special sharps (puncture proof) container nearby for disposing of used needles and syringes.

For your protection, it is important that you follow these instructions.

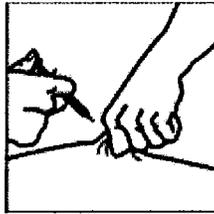
2) Choosing and preparing an injection site



- Wash your hands well
- Choose a site on the front of your thighs or your stomach area (abdomen). If you choose your abdomen, you should avoid the area 2 inches around your belly button (navel).
 - Choose a different site each time you give yourself an injection. Each new injection should be given at least one inch from a site you used before. **Never** inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.
 - If you have psoriasis, you should try not to inject directly into any raised, thick, red or scaly skin patches or lesions.
 - You may find it helpful to keep notes on the location of your injection sites.
- Wipe the site where HUMIRA is to be injected with an alcohol prep (swab), using a circular motion. **Do not** touch this area again until you are ready to inject.

3) How to prepare your HUMIRA dose for injection with a Prefilled Syringe

- Hold the syringe upright with the needle facing down. Check to make sure that the amount of liquid in the syringe is the same or close to the 0.8 mL line for the 40 mg prefilled syringe or the 0.4 mL line for the 20 mg pediatric prefilled syringe. The top of the liquid may be curved. If the syringe does not have the correct amount of liquid, **do not use that syringe**. Call your pharmacist.
- Remove the needle cover taking care not to touch the needle with your fingers or allow it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle that is okay. Do not shake the syringe.



4) Injecting HUMIRA

- With your other hand, gently squeeze an area of the cleaned area of skin and hold it firmly. You will inject into this raised area of skin. Hold the syringe like a pencil at about a 45° angle (see picture) to the skin.
- With a quick, short, “dart-like” motion, push the needle into the skin.
- After the needle is in, let go of the skin. Pull back slightly on the plunger. If blood appears in the syringe it means that you have entered a blood vessel. Do not inject HUMIRA. Pull the needle out of the skin and repeat the steps to choose and clean a new injection site. **Do not** use the same syringe. Dispose of it in your special sharps container. If no blood appears, slowly push the plunger all the way in until all of the HUMIRA is injected.
- When the syringe is empty, remove the needle from the skin keeping it at the same angle it was when it was pushed into the skin.
- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **not** rub the injection site. You may have slight bleeding. This is normal.
- Dispose of the syringe right away into your special sharps container. (See “**How Do I Dispose of Syringes and Needles?**”)

How Do I Dispose of Syringes and Needles?

You should always check with your doctor's office for instructions on how to dispose of used needles and syringes. You should follow any special state or local laws regarding the disposal of needles and syringes. **Do not throw the needle or syringe in the household trash or recycle trash.**

- Place the used needles and syringes in a container made specially for disposing of used syringes and needles (called a “Sharps” container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labeled “Used Syringes”. Do not use glass or clear plastic containers.
- **Always keep the container out of the reach of children.**
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your doctor, nurse or pharmacist. **Do not throw the container in the household trash or recycle trash.**

- Used alcohol pads may be placed in the trash, unless otherwise instructed by your doctor, nurse or pharmacist. The dose tray and cover may be placed in your recycle trash.

Rev. 02/2011

U.S. Govt. Lic. No. 0043

Abbott Laboratories

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